

Federal Advisory Committee (FAC) Membership Balance Plan

Please read the Federal Advisory Committee Membership Balance Plan Guidance prior to completing this form

GENERAL SERVICES ADMINISTRATION
(1) FEDERAL ADVISORY COMMITTEE NAME <i>State the legal name of the FAC</i>
Advisory Committee on Organ Transplanatation
(2) AUTHORITY <i>Identify the authority for establishing the FAC</i>
<p>42 U.S.C. 217a; Section 222 of the Public Health Service Act, as amended; 42 CFR 121.12. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.</p>
(3) MISSION/FUNCTION <i>Describe the mission/function of the FAC</i>
<p>The Committee advises the Secretary, acting through the Administrator, Health Resources and Services Administration (HRSA), on all aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines. One of its principal functions is to advise the Secretary on Federal efforts to maximize the number of deceased donor organs made available for transplantation and to support the safety of living organ donation.</p> <p>The Committee, at the request of the Secretary, reviews significant proposed OPTN policies submitted for the Secretary's approval to recommend whether they should be made enforceable. It provides expert input to the Secretary on the latest advances in the science of transplantation, the OPTN's system of collecting, disseminating and ensuring the validity, accuracy, timeliness and usefulness of data, and additional medical, public health, patient safety, ethical, legal, financial coverage, social science, and socioeconomic issues that are relevant to transplantation.</p>
(4) POINTS OF VIEW <i>Based on understanding the purpose of the FAC,</i> <i>(a) describe the process that will be used to ensure the committee is balanced, and identify the categories (e.g. individual expertise or represented interests) from which candidates will be considered;</i> <i>(b) consider identifying an anticipated relative distribution of candidates across the categories; and</i> <i>(c) explain how a determination was made to appoint any individuals as Special Government Employees or Representative members</i>
<p>The Committee shall consist of up to 25 members, who are Special Government Employees, and 6 ex-officio, non-voting members. Members and the Chair are appointed by the Secretary from individuals knowledgeable in such fields as deceased and living organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, living organ donors, and family members of deceased and living organ donors. To the extent practicable, Committee members represent the minority, gender and geographic diversity of transplant candidates, transplant recipients, organ donors and family members served by the OPTN.</p> <p>The ex-officio, non-voting members should include the Directors of the National Institutes of Health, the Centers for Disease and Prevention, and the Agency for Healthcare Research and Quality; the Administrator of the Centers for Medicare and Medicaid Services; the Commissioner of</p>

the Food and Drug Administration; and the Chair of the Advisory Committee on Blood Safety and Availability – or their designees. The Secretary also may appoint other non-voting ex-officio members, or designees of such officials, as the Secretary deems necessary for the Committee to effectively carry out its function.

An initial review of nominees is made by a panel of experts from the Division of Transplantation. That group then makes recommendations to the Associate Administrator who provides recommendations to the Administrator. The HRSA Administrator recommends the slate of nominees to the Secretary. The final determination is based on the best qualified nominees to fill the Committee vacancies based on the requirements set in regulation and in the charter.

(5) OTHER BALANCE FACTORS

List any other factors your agency identifies as important in achieving a balanced FAC

The Department will give close attention to equitable geographic distribution and to minority and female representation. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, HIV status, disability, and cultural, religious, or socioeconomic status.

(6) CANDIDATE IDENTIFICATION PROCESS

Summarize the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance. The summary should:

- (a) describe the process*
- (b) identify the agency key staff involved (by position, not name)*
- (c) briefly describe how FAC vacancies, if any, will be handled by the agency; and*
- (d) state the membership term limit of FAC members, if applicable*

As members rotate off the Committee, suggestions for members are sought, generally through a Federal Register notice. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership. During the year, suggestions for membership to the Committee are received from various sources. These submissions are compiled for consideration along with those received from the solicitation.

A listing of individuals nominated for service on the Committee is prepared by the Designated Federal Officer (DFO) of ACOT and forwarded to an internal review committee, composed of Bureau, Agency, and/or Department staff, for review and a final selection of a proposed slate of candidates.

The final nomination package is submitted to the Secretary, HHS, who appoints the member(s) to the Committee. Formal letters of invitation to serve on the Committee are extended by the Secretary.

Members are invited to serve for 4-year terms. Members shall not serve while they are also serving on the OPTN Board of Directors.

A member who is unable to fulfill the full term on the Committee may resign by submitting his/her resignation in writing to the DFO of ACOT. A vacancy on the Committee is filled in the manner in which the original appointment was made and is subjected to any conditions that applied with respect to the original appointment. An individual chosen to fill a vacancy is appointed for the remainder of the term of the member replaced. The vacancy will not affect the power of the remaining members to execute the duties of the Committee.

(7) SUBCOMMITTEE BALANCE

Subcommittees subject to FACA should either state that the process for determining FAC member balance on subcommittees is the same as the process for the parent FAC, or describe how it is different*

**This is relevant to those agencies that require their subcommittees to follow all FACA requirements.*

The process for determining Federal Advisory Committee member balance on subcommittees is the same process for the parent Federal Advisory Committee.

(8) OTHER

Provide any additional information that supports the balance of the FAC

None.

(9) DATE PREPARED/UPDATED

Insert the actual date the Membership Balance Plan was initially prepared, along with the date(s) the Plan is updated

August 9, 2016